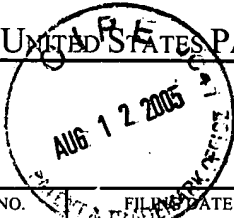


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ATY ENW



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
.09/810,865	03/16/2001	Stephen J. Brown	HERO-1-1112	6556

26111 7590 07/26/2005

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

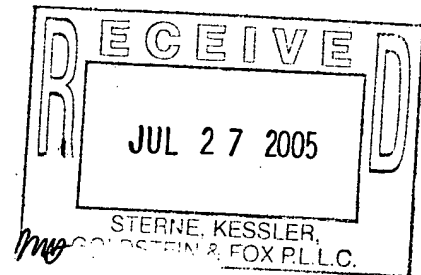
PHAN, THAI Q

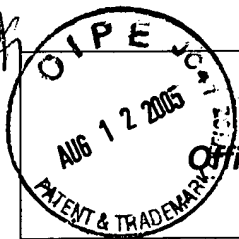
ART UNIT	PAPER NUMBER
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2128

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.





Office Action Summary

Application No.	Applicant(s)	
09/810,865	BROWN, STEPHEN J.	
Examiner	Art Unit	
Thai Q. Phan	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Apr/ May 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

PD



DETAILED ACTION

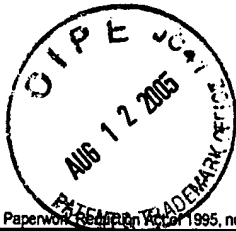
This Office Action is in response to applicant's amendment filed on 08/09/2004. Claims 1-36 were cancelled. New claims 37-66 have been added.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37-66 are rejected under 35 U.S.C. 112, first paragraph, because the best mode with the enablement requirement contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the claims require a feature of "to prevent hypoglycemia or hyperglycemia", "a supplemental insulin bolus dose", "insulin action remaining", "a fraction of insulin action" and "target blood glucose value will fall outside the target range" as cited in claim 55. The specification does not describe and provide the analysis for how the self-care control parameters, control parameters and control mechanisms would be able to prevent the complicate disease such as hypoglycemia or hyperglycemia, determining insulin action remaining, a faction of insulin action, a supplemental insulin bolus dose, etc. as claimed. This subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and use the invention.



PTO/SB/122 (04-05)

Approved for use through 07/31/2006. OMB 0651-0035

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

CHANGE OF CORRESPONDENCE ADDRESS Application Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	09/810,865-Conf. #6556
	Filing Date	March 16, 2001
	First Named Inventor	Stephen Brown
	Art Unit	2128
	Examiner Name	Phan, Thai Q.
	Attorney Docket No.	014030.0123N2US

Please change the Correspondence Address for the above-identified application to:

☒ The address associated with Customer Number:

OR

<input type="checkbox"/> Firm or Individual Name				
Address				
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Country				
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This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).

I am the:

- ☐ Applicant/Inventor
- ☐ Assignee of record of the entire interest.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).
- ☒ Attorney or agent of record. Registration Number 41,567
- ☐ Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number _____

Signature	
Typed or Printed Name	Scott W. Cummings
Date	July 13, 2005
Telephone	(730) 744-8000

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

<input type="checkbox"/> *Total of <u>1</u> forms are submitted.
--

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 37-66 are rejected under the judicially created doctrine of double patenting over claims 1-32 of U. S. Patent No. 5,956,501 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a system and device output for outputting a signal configured in a simulation of the self-care action according to at least one self care control parameters of a patient. The claims in US patent no. 5,956,501 are to control and prevent a disease. Although the conflicting claims are not identical, they are not patentably distinct from each other because the disease control and simulation in the patent claims would be for controlling a

Art Unit: 2128

plurality of diseases and would implicitly include the claimed limitations to prevent other disease such as hyperglycemia or hypoglycemia.

Response to Arguments

Applicant's arguments with respect to new claims 37-66 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US patent no. 5,733,259, issued to Valcke et al, on Mar. 1998

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 2128

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thai Q. Phan whose telephone number is 571-272-3783. The examiner can normally be reached on Monday-Friday.

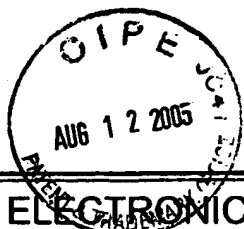
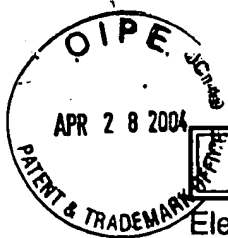
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jean Homere can be reached on 571-272-3780. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 30, 2005




Thai Phan
Patent Examiner



ELECTRONIC INFORMATION DISCLOSURE STATEMENT

Electronic Version v18
Stylesheet Version v18.0

Title of Invention	DISEASE SIMULATION SYSTEM AND METHOD	
Application Number: Confirmation Number: First Named Applicant: Attorney Docket Number: Art Unit: Examiner: Search string:	09/810865 6556 Stephen Brown 6858P014X5 2128 Thai Phan (3426150 or 3566365 or 3566370 or 3768014 or 3910257 or 3920005 or 3996928 or 4004577 or 4130881 or 4150284 or 4151407 or 4151831 or 4173971 or 4216462 or 4227526 or 4253521 or 4259548 or 4270547 or 4296756 or 4347568 or 4347851 or 4360345 or 4417306 or 4422081 or 4449536 or 4465077 or 4473884 or 4519398 or 4531527 or 4546436 or 4566461 or 4576578 or 4592546 or 4627445 or 4674652 or 4686624 or 4694490 or 4695954 or 4712562 or 4722349 or 4729381 or 4731726 or 4768229 or 4779199 or 4782511 or 4796639 or 4799199 or 4803625 or 4835372 or 4838275 or 4858354 or 4858617 or 4890621 or 4897869 or 4907973 or 4933873 or 4950246 or 4953552 or 4958632 or 4958641 or 4967756 or 4977899 or 4979509 or 5007429 or 5016172 or 5019974 or 5024225 or 5025374 or 5034807 or 5036462 or 5049487 or 5050612 or 5056059 or 5059394 or 5065315 or 5068536 or 5074317 or 5077476 or 5095798 or 5109414 or 5109974 or 5111396 or 5111817 or 5111818 or 5120230 or 5120421 or 5128752 or 5134391 or 5142358 or 5142484 or 5176502 or 5182707 or 5204670 or 5222020 or 5227874 or 5228450 or 5231990 or 5249044 or 5251126 or 5261401 or 5262943 or 5265888 or 5266179 or 5275159 or 5282950 or 5299121 or 5301105 or 5304468 or 5307263 or 5309919 or 5329459 or 5329608 or 5331549 or 5339821 or 5341291 or 5343239 or 5344324 or 5357427 or 5366896 or 5371687 or 5375604 or 5377100 or 5390238 or 5399821 or 5410471 or 5410474 or 5429140 or 5431691	

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or 6055487 or 6055506 or 6057758 or 6110148
or 6138145 or 6151586 or 6168563 or 6177940
or 6189029 or 6221012 or 6248065 or
6368273).pn.

US Patent Documents

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
T.P.	1	3426150	1969-02-04	Tygart, William H.			
A	2	3566365	1971-02-23	Rawson, Edward B., et al.			
	3	3566370	1971-02-23	Worthington, Jr., Harvey , et al.			
	4	3768014	1973-10-23	Smith,			
	5	3910257	1975-10-07	Fletcher, James C., et al.			
	6	3920005	1975-11-18	Gombrich, Peter P., et al.			
	7	3996928	1976-12-14	Marx, Alvin J.			

8	4004577	1977-01-25	Sarnoff, Stanley J.
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10	4150284	1979-04-17	Trenkler, George , et al.
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12	4151831	1979-05-01	Lester, Robert W.
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14	4216462	1980-08-05	McGrath, William J., et al.
15	4227526	1980-10-14	Goss, Jack
16	4253521	1981-03-03	Savage, Ronald E.
17	4259548	1981-03-31	Fahey, Robert J., et al.
18	4270547	1981-06-02	Steffen, Dale A., et al.
19	4296756	1981-10-27	Dunning, Ted E., et al.
20	4347568	1982-08-31	Giguere, Edward L., et al.
21	4347851	1982-09-07	Jundanian, Richard H.
22	4360345	1982-11-23	Hon, David
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24	4422081	1983-12-20	Woods, Donald C., et al.
25	4449536	1984-05-22	Weaver, Charles S.
26	4465077	1984-08-14	Schneider, Howard
27	4473884	1984-09-25	Behl, Robert S.
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30	4546436	1985-10-08	Schneider, Wolfger , et al.
31	4566461	1986-01-28	Lubell, Michael , et al.
32	4576578	1986-03-18	Parker, Robert R., et al.
33	4592546	1986-06-03	Fascenda, Anthony C., et al.
34	4627445	1986-12-09	Garcia, S. F.
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36	4686624	1987-08-11	Blum, D., et al.
37	4694490	1987-09-15	Harvey, John C., et al.
38	4695954	1987-09-22	Rose, Robert J., et al.
39	4712562	1987-12-15	Ohayon, Jacques J., et al.
40	4722349	1988-02-02	Baumberg, Iosif
41	4729381	1988-03-08	Harada, Chikao , et al.
42	4731726	1988-03-15	Allen, III, Lyle M.
43	4768229	1988-08-30	Benjamin, Lester F., et al.

44	4779199	1988-10-18	Yoneda, Kiwamu , et al.
45	4782511	1988-11-01	Nemec, , et al.
46	4796639	1989-01-10	Snow, Michael G., et al.
47	4799199	1989-01-17	Scales, III., Hunter L., et al.
48	4803625	1989-02-07	Fu, Ping W., et al.
49	4835372	1989-05-30	Gombrich, Peter P., et al.
50	4838275	1989-06-13	Lee, Arnold S.
51	4858354	1989-08-22	Gettler, Lawrence H.
52	4858617	1989-08-22	Sanders, William J.
53	4890621	1990-01-02	Hakky, Said I.
54	4897869	1990-01-30	Takahashi, Masatomo
55	4907973	1990-03-13	Hon, David C.
56	4933873	1990-06-12	Kaufman, Stephen B., et al.
57	4950246	1990-08-21	Muller, Robert H.
58	4953552	1990-09-04	DeMarzo, Arthur P.
59	4958632	1990-09-25	Duggan, Stephen R.
60	4958641	1990-09-25	Digby, Dennis , et al.
61	4967756	1990-11-06	Hewitt, Terry L.
62	4977899	1990-12-18	Digby, Dennis , et al.
63	4979509	1990-12-25	Hakky, Said I.
64	5007429	1991-04-16	Treatch, James E., et al.
65	5016172	1991-05-14	Dessertine, Albert L.
66	5019974	1991-05-28	Beckers, Andreas G.
67	5024225	1991-06-18	Fang, William
68	5025374	1991-06-18	Roizen, Michael , et al.
69	5034807	1991-07-23	Von Kohorn, Henry
70	5036462	1991-07-30	Kaufman, Stephen B., et al.
71	5049487	1991-09-17	Phillips, Roger , et al.
72	5050612	1991-09-24	Matsumura, Kenneth N.
73	5056059	1991-10-08	Tivig, Gerhard , et al.
74	5059394	1991-10-22	Phillips, Roger , et al.
75	5065315	1991-11-12	Garcia, Angela M.
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79	5095798	1992-03-17	Okada, Saturo , et al.

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83	5111817	1992-05-12	Clark, Justin S., et al.
84	5111818	1992-05-12	Suzuki, Arata , et al.
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86	5120421	1992-06-09	Glass, Robert S., et al.
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88	5134391	1992-07-28	Okada, Saturo
89	5142358	1992-08-25	Jason, Leonard A.
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93	5204670	1993-04-20	Stinton, Vincent D.
94	5222020	1993-06-22	Takeda, Fumihide
95	5227874	1993-07-13	Von Kohorn, Henry
96	5228450	1993-07-20	Sellers, Craig S.
97	5231990	1993-08-03	Gauglitz, Karl F.
98	5249044	1993-09-28	Von Kohorn, henry
99	5251126	1993-10-05	Kahn, Michael G., et al.
100	5261401	1993-11-16	Baker, James , et al.
101	5262943	1993-11-16	Thibado, Michael J., et al.
102	5265888	1993-11-30	Yamamoto, Masao , et al.
103	5266179	1993-11-30	Nankai, Shiro , et al.
104	5275159	1994-01-04	Griebel, Peter
105	5282950	1994-02-01	Dietze, Werner
106	5299121	1994-03-29	Brill, Albert R., et al.
107	5301105	1994-04-05	Cummings, Jr., Desmond D.
108	5304468	1994-04-19	Phillips, Roger
109	5307263	1994-04-26	Brown, Stephen J.
110	5309919	1994-05-10	Snell, Jefferey D., et al.
111	5329459	1994-07-12	Kaufman, Stephen B., et al.
112	5329608	1994-07-12	Bocchiere, Enrico L., et al.
113	5331549	1994-07-19	Crawford, Jr., John M.
114	5339821	1994-08-23	Fujimoto, Jun
115	5341291	1994-08-23	Roizen, Michael , et al.

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117	5344324	1994-09-06	O'Donnell, Robert D., et al.
118	5357427	1994-10-18	Langen, Pauline A., et al.
119	5366896	1994-11-22	Margrey, Keith S., et al.
120	5371687	1994-12-06	Holmes, II, John S., et al.
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122	5377100	1994-12-27	Pope, Alan T., et al.
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125	5410471	1995-04-25	Alyfuku, Kiyoshi , et al.
126	5410474	1995-04-25	Fox, David
127	5429140	1995-07-04	Burdea, Grigore C., et al.
128	5431691	1995-07-11	Snell, Jeffery D., et al.
129	5434611	1995-07-18	Tamura, Masakatsu
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132	5454721	1995-10-03	Kuch, Nina J.
133	5454722	1995-10-03	Holland, Simon , et al.
134	5456606	1995-10-10	McIntyre, Kevin M.
135	5456692	1995-10-10	Smith, Jr., Robert E., et al.
136	5458123	1995-08-17	Unger, John D.
137	5467269	1995-11-14	Flaten, Lawrence M.
138	5471039	1995-11-28	Irwing, Jr., kenneth E., et al.
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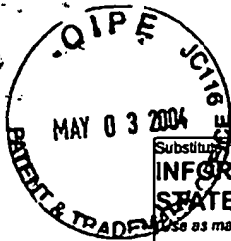
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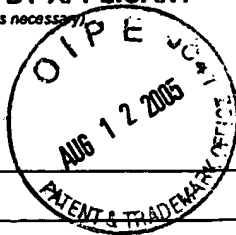
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Application Number	09/810,865
Filing Date	March 16, 2001
First Named Inventor	Stephen J. Brown
Group Art Unit	2128
Examiner Name	Thai Phan

Attorney Docket No: 006858P014X5

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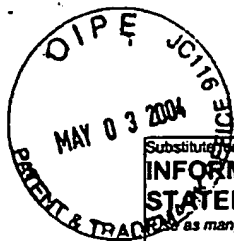
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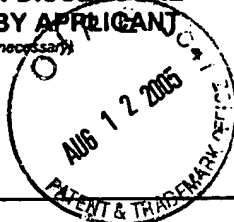
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Application Number	09/810,865
Filing Date	March 16, 2001
First Named Inventor	Stephen J. Brown
Group Art Unit	2128
Examiner Name	Thai Phan

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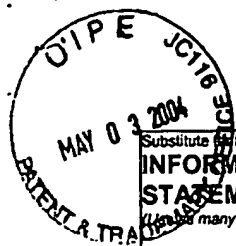
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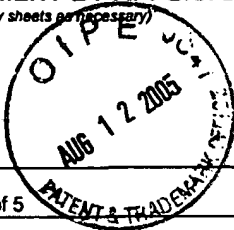
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Application Number 09/810,865

Filing Date March 16, 2001

First Named Inventor Stephen J. Brown

Group Art Unit 2128

Examiner Name Thai Phan

Attorney Docket No: 006858P014X5

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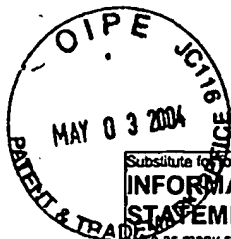
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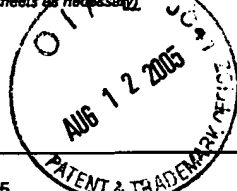
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Application Number 09/810,865

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First Named Inventor Stephen J. Brown

Group Art Unit 2128

Examiner Name Thai Phan

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T.P.	✓	Respir. Crit. Care Med., (1997), Vol. 156, pp. S117-S122	
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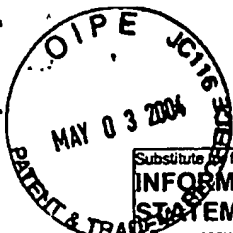
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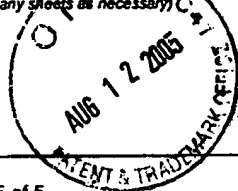
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Application Number	09/810,865
Filing Date	March 16, 2001
First Named Inventor	Stephen J. Brown
Group Art Unit	2128
Examiner Name	Thai Phan

Sheet 5 of 5

Attorney Docket No: 006858P014X5

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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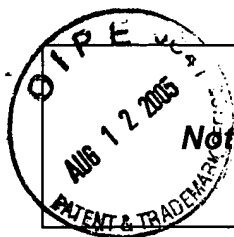
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**Notice of References Cited**

Application/Control No.

09/810,865

Applicant(s)/Patent Under
Reexamination
BROWN, STEPHEN J.

Examiner

Thai Q. Phan

Art Unit

2128

Page 1 of 1

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